U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 24, 2020

To: Anita Chang, Ph.D. Division of Food Contact Substances (HFS-275)
Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2100: an aqueous mixture of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), sulfuric acid (CAS Reg. No. 7664-93-9), and 1-hydroxyethylidine-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4) as an antimicrobial agent for use as a spray on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), edible seeds (chia, flax, hemp, millet hulled, pumpkin, sesame, sunflower kernel, and quinoa), nuts (almond, cashew, walnut, brazil nuts, hazelnuts, macadamia and pecans), and all spices.

Notifier: Agri-Neo Inc.

Attached is the FONSI for FCN 2100, which is for the use of an aqueous mixture of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), sulfuric acid (CAS Reg. No. 7664-93-9), and 1-hydroxyethylidine-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4) as an antimicrobial agent for use as a spray on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), edible seeds (chia, flax, hemp, millet hulled, pumpkin, sesame, sunflower kernel, and quinoa), nuts (almond, cashew, walnut, brazil nuts, hazelnuts, macadamia and pecans), and all spices. The FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this FCN becomes effective, copies of this FONSI, the notifier's environmental assessment (EA), dated November 4, 2020, and the EA Revision Sheet may be made available to the public. We will post digital transcriptions of the FONSI, EA, and revision sheet on the agency's public website.

Please let us know if there is any change in the identity or use of the food-contact substance.

Antonetta Thompson-Wood

Attachments: Finding of No Significant Impact (FONSI), EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2100, submitted by Agri-Neo Inc. for the use of an aqueous mixture of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), sulfuric acid (CAS Reg. No. 7664-93-9), and 1-hydroxyethylidine-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4) as an antimicrobial agent for use as a spray on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), edible seeds (chia, flax, hemp, millet hulled, pumpkin, sesame, sunflower kernel, and quinoa), nuts (almond, cashew, walnut, brazil nuts, hazelnuts, macadamia and pecans), and all spices. The components of the FCS on seeds or nuts will not exceed 229 parts per million (ppm) peroxyacetic acid, 1043 ppm hydrogen peroxide, 388 ppm acetic acid, 48 ppm sulfuric acid, and 25 ppm HEDP. The FCS will be applied in the preparing, packing, or holding of the food for commercial purposes, consistent with the FD&C Act section 201(q)(1)(B)(i). The treated edible seeds can be consumed directly or further processed into flour, protein, or oil. The treated edible nuts are intended to be consumed as nuts. The treated seeds for sprouting are intended to be consumed as sprouts. The treated spices may be consumed directly.

The FCS is not intended for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

The Office of Food Additive Safety has determined that allowing this notification to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement (EIS) will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA), dated November 4, 2020. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI) and is briefly summarized below.

The antimicrobial agent is needed to inhibit the growth of undesirable or pathogenic microorganisms on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), edible seeds (chia, flax, hemp, millet hulled, pumpkin, sesame, sunflower kernel, and quinoa), nuts (almond, cashew, walnut, brazil nuts, hazel nuts, macadamia and pecans), and all spices.

When used in food processing plants, the waste process water containing the FCS is expected to enter the wastewater treatment unit at the plants. Treated wastewater will be discharged directly to the surface waters in accordance with the plants' National Pollutant Discharge Elimination System (NPDES) permit.

Treatment of the process water at an on-site wastewater treatment plant is expected to result in the complete degradation of PAA, HP, and AA. Specifically, the PAA will breakdown into oxygen, and AA, while HP will break down into oxygen and water. AA is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water. Sulfuric acid dissociates readily in water to sulfate ions and hydrated protons. As part of the sulfur cycle, sulfate is either incorporated into living organisms, reduced via anaerobic biodegradation to sulfides, deposited as sulfur, or re-oxidized to sulfur dioxide and sulfate. Therefore, the EA focuses on the environmental impacts of HEDP.

The use level of 25 ppm for HEDP is the maximum concentration of HEDP that may be expected in a worst-case scenario. HEDP is a chelating agent and exhibits unique partitioning behavior such that 80% adsorbs to wastewater treatment sludge, while the remaining 20% stays in the water. Applying the 80:20 partitioning factors yields an environmental introduction concentration (EIC) in sludge of 25 ppm x 0.8 = 20 ppm. The aquatic EIC is 25 ppm x 0.2 = 5 ppm. In order to arrive at the effective environmental concentration (EEC) in water, a 10-fold dilution factor is applied to the HEDP that remains in water to account for dilution upon release to surface water (EIC ÷ 10 = EEC). Therefore, the aquatic EEC is 5 ppm ÷ 10 = 0.5 ppm.

HEDP shows no toxicity to terrestrial organisms at levels up to 1,000 mg/kg (ppm) soil dry weight (No Observed Effect Concentration; NOEC]), and the lowest relevant endpoint for aquatic toxicity was determined to be the chronic NOEC of

10 to <12.5 ppm for Daphnia magna. Therefore, there is no toxicity expected from land application of sludge containing 20 ppm HEDP. The surface water EEC for HEDP (0.5 ppm) is within the NOEC range of the most sensitive aquatic endpoint. Based on the comparison of the EECs against aquatic toxicity endpoints, in conjunction with the fact that the EECs were derived based on a conservative assumption that 100% of the FCS used at a facility enters an on-site or off-site wastewater treatment system, adverse environmental effects to aquatic organisms are not expected.

Use of the FCS is not expected to cause a significant impact on resources and energy. No mitigation measures are needed since no adverse impacts are expected from use of the FCS. The alternative to not allowing the FCN to become effective would be continued use of currently approved antimicrobial agents; such action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2100 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 11-24-2020
Antonetta Thompson-Wood
Physical Scientist, Environmental Team
Office of Food Additive Safety,
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 12-03-2020
Mariellen Pfeil
Lead Biologist, Environmental Team
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U.S. Food and Drug Administration
Revision Sheet for the November 4, 2020 EA for FCN 2100

Revision Sheet Dated: November 24, 2020

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) dated November 4, 2020 for food contact notification (FCN) 2100 concluded that the action will not constitute a significant impact. This revision is issued to make minor changes and updates of an editorial nature that should be acknowledged, while not making any substantive changes to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The need for this revision sheet is to correct errors resulting from an apparent typographical error in the stating of the at-use HEDP concentration from 25 ppm to 540 ppm. This error was introduced by the notifier during the EA drafting and iterative review process and was not noticed. As such, the following EA revisions are required:

Revision 1

Page 3 states:
"These commodities may be treated with the FCS only once and at a maximum use rate of 4 L of Neo-Pure® per 1 ton (1000kg) of commodity (max 0.4%)" "

And that:
"A maximum amount of 4 L of Neo-Pure® is diluted in water or water ethanol (80:20) mixture to prepare a total volume of 40 L of diluted FCS solution and applied to 1 ton of spices, seeds for sprouting, edible seeds or nuts. Twenty-four hours after treatment, the treated commodities are dried."

These statements should not be included in this item of the EA because it is not reflected in the final language for this notification

Revision 2

Page 8 indicates that:

1. the maximum HEDP EIC (pre-treatment wastewater) is 540 ppm
2. 80% partition to sludge during WWT 0.80 x 540 ppm = 432 pm EIC (sludge), and
3. (that 20% partition to water during WWT 0.20 x 540 ppm = 108 ppm EIC (effluent)

Because the maximum HEDP usage is 25 ppm, this language should state:

1. the maximum HEDP EIC (pre-treatment wastewater) is ***25*** ppm,
2. 80% partition to sludge during WWT ***0.80 x 25 ppm = 20 ppm*** EIC (sludge), and
3. that 20% partition to water during WWT ***0.20 x 25 ppm = 5 ppm*** EIC (effluent)

Revision 3

From the above, Page 8 Table 1 (HEDP Expected Introduction Concentrations in Effluent and Sludge) is revised to

Use	**HEDP Maximum $EIC_{pre\text{-}treatment\ wastewater}$ (ppm)**	**$EIC_{effluent}$ (ppm)**	**EIC_{sludge} (ppm)**
Spray on spices, seeds for sprouting, edible seeds, and nuts	25	5	20

Revision 4

From the above, Page 11 is revised to:

1. HEDP EIC (pre-treatment wastewater) is ***25*** ppm,
2. 80% partition to sludge during WWT ***0.80 x 25 ppm = 20 ppm*** EIC sludge and EEC sludge,
3. 20% partition to water during WWT ***0.20 x 25 ppm = 5 ppm*** EIC (effluent), and
4. Discharge per NPDES Permit or POTW EIC/dilution factor = ***5 ppm / 10 = 0.5ppm*** EEC (surface water)

Revision 5

From the above, Page 12 is revised to:
"In order to evaluate the expected environmental concentration (EEC) of HEDP in surface water, a 10-fold dilution factor is applied to the aquatic EIC (EIC = 5 ppm). Therefore, the EEC of HEDP from the proposed use is estimated to be 0.5 ppm in surface waters directly receiving the treated effluent."

And that
"The EEC of HEDP from the proposed use is estimated to be 20 ppm in sludge following on-site wastewater treatment".

Revision 6

From the above, Page 12, Table 3 (Maximum Expected Introduction Concentrations, an Expected Environmental Concentrations for HEDP) is revised to:

Use	**HEDP Maximum $EIC_{pre\text{-}treatment\ wastewater}$ (ppm)**	**$EIC_{effluent}$ (ppm)**	**EIC_{sludge} (ppm)**	**EEC_{water} (ppm)**	**EEC_{sludge} (ppm)**
Spray on spices, seeds for sprouting, edible seeds, and nuts	25	5	20	0.5	20

Revision 7

From the above, Page 14 is revised to:
"When compared against the 28-day Daphnia NOEC range of 10 < 12.5 ppm, the surface water EEC for HEDP (0.5) is within the NOEC range of the most relevant sensitive aquatic toxicity endpoint."

And that

"The worst-case theoretical EEC of HEDP in sludge is 20 ppm, which is within the range of no effects among most sensitive terrestrial endpoints".